

**REMARKS**

***Status of Claims***

Claims 1-3, 5, 8, 11, 14-22, 25, 28-31, and 34-48 are currently pending. The Examiner omitted claim 8 from the list of pending claims in the Office Action. Applicants assert that claim 8 is also currently pending in this application. Applicants respectfully request reconsideration of the rejections and allowance of the pending claims.

***Information Disclosure Statement***

The Office Action indicates that the references cited on the IDS filed January 21, 2004 have not been considered by the examiner. The record shows, however, that these references were considered by the examiner on March 8, 2007. Applicants wish to thank the examiner for consideration of these references.

***Drawings***

The Examiner objected to the drawings because reference character 46 does not appear in the description. In response, Applicants have amended paragraph 59 of the specification to include 46 as showing a cover that reservoir 48 is positioned upon. Applicants submit that this amendment to the specification overcomes the Examiner's objection.

***Reply to Rejections Under 35 U.S.C. § 102(b)***

Claims 1-3, 5-6, 11, 14-22, 25, 28-31, and 34, and 46-48 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Stasz, U.S. Patent No. 5,311,875. Applicants respectfully submit that Stasz fails to teach all the claim elements of the present claims. For example, Stasz at least fails to disclose a sensor for detecting movement of air comprising at least one flexible lead connecting the substrate to a mounting portion of the sensor.

Also, Stasz does not teach a substrate and flexible lead which are displaceable in the presence of a stream of moving gas or liquid causing flexure of the transducer and changing the electrical value of the transducer. Stasz teaches a transducer that changes in electrical value in response to temperature changes and sound.

The transducer provides a low frequency output signal proportional to change in temperature during the impingement of respiratory gases thereon as well as a relatively higher frequency output voltage which is proportional to sound level, such as may be produced.<sup>1</sup>

Stasz does not teach a transducer that changes in electrical value in response to a stream of moving gas and liquid and also does not teach a substrate and flexible lead displaceable in such a stream. Accordingly, Stasz can not anticipate the present claims. Applicants respectfully request withdrawal of this rejection.

Claims 35-45 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Ritson, U.S. Patent No. 5,522,378. Applicants respectfully submit that Ritson fails to teach all the claim elements of the present claims. For example, Ritson at least fails to disclose a sensor for detecting movement of air, wherein the sensor is positioned in the airway proximate the air inlet such that the sensor is effective to selectively close the air inlet.

Rather, Ritson discloses that the durable body of the Ritson device includes a flow sensor having an asymmetrical orifice that is calibrated, independent of the cassette, to convert the sensed pressure due to flow into a flow rate. The other port is connected by tube 520 to the pressure tap 516 which is located within airway 601, preferably on ramp 511 (see FIG. 18c). At no point is the air inlet selectively closed. The following passages are instructive for determining the mechanism by which the Ritson device operates.

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<sup>1</sup> See Statz at column 2, lines 13-19.

Referring to FIGS. 3, 16D, 18B and 18C, flow transducer system 600 includes a pressure transducer 505, a durable flow measurement section having a contoured surface built into wall 506 at the bottom of housings 11 and 12, airway cover 13, and a pressure port 516. Preferably, the contour of wall 506 is flat in the cross section end view as shown in FIG. 18C. Airway 601 mates with the airflow path 24 (through mouthpiece 20 end 23 and top end opening 29 the lower portion of 45 of housing 40, and out aperture 43). Airway 601 comprises the bottom wall 506, made of the mated housings 11 and 12, and airway cover 13.

In operation of the present invention, as the patient inhales or exhales through the device, flow through path 601 is sensed at pressure tap 516 in wall 506 and at atmospheric pressure (not shown) by pressure transducer 505. The output signal of transducer 505 is converted to a digital value by control electronics 50 at a selected sampling rate and integrated at that sampling rate to obtain inhaled or exhaled volume. Drug dispensation timing and therapeutic decisions are based upon these measurements of flow rate and volume.

Ritson at Column 25, line 60 to column 26 line 12.

A preferred flow sensing transducer 505 used to measure these pressure changes is a resistive strain-gauge type device having two ports. One port is vented to ambient pressure. The other port is connected by tube 520 to the pressure tap 516 which is located within airway 601, preferably on ramp 511 (see FIG. 18c). Pressure changes at the airway port 516 cause the resistances within sensor 505 to change. These resistance changes are provided in the form of a variable voltage output which is digitized by control electronics 50. The digital value is converted to a corresponding flow value using the predetermined calibration look-up table stored in the system memory PROM, ROM, or nonvolatile RAM. One suitable transducer 505 is model NPH-8-002.5DH, available from Lucas Nova sensor, Fremont, Calif.

Pressure sensor 505 of this type are known to suffer from several problems. First, the devices exhibit thermal and long-term drift, causing the output signal to wander slightly after power-up. The output signal also varies with the orientation of the sensor. Normally, these effects would be negligible. However, in the application of the present invention, the parabolic nature of the flow-pressure curve makes the accuracy of look-up table conversion very sensitive to these offset changes. This is because, at low flow rates, a very small change in the pressure signal maps into a relatively large change in the calculated flow rate.

Ritson at Column 29, lines 33-57.

The above passages and referenced figures therein show that Ritson does not contemplate the selective closure of the airway. Accordingly, Ritson cannot anticipate the present claims. Applicants respectfully request withdrawal of this rejection.

**CONCLUSION**

An indication of allowance of all claims is respectfully solicited. Early notification of a favorable consideration is respectfully requested. In the event any issues remain, Applicant would appreciate the courtesy of a telephone call to their counsel to resolve such issues and place all claims in condition for allowance.

It is believed that no additional fees are required with this submission. However, in the event that additional fees are deemed necessary, or in the event of any variance between the amount enclosed and the fees determined by the USPTO, please charge or credit any such variance to the undersigned's Deposit Account No. 50-0311, Reference No. 35056-512.

Respectfully submitted,

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